

AUG 21 2002

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K022605

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Name of Firm:** Blackstone Medical, Inc.  
90 Brookdale Drive  
Springfield, MA 01104

**510(k) Contact:** Alan Lombardo  
Director of Engineering

**Trade Name:** Blackstone™ Spinal Fixation System  
Staple & Washer (System Addition)

**Common Name:** Rod and screw spinal instrumentation

**Device Product Code  
& Classification:** KWQ 888.3060 - Spinal Intervertebral Body Fixation  
Orthosis

**Substantially**

**Equivalent Devices:** Blackstone™ Spinal Fixation System (K994217)  
Blackstone™ Spinal Fixation System Second-Gen Cross-  
Connector (K003735)  
Blackstone™ Spinal Fixation System 4.5mm Mono-Axial  
Screws (K013558)  
Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws  
(K020674)

**Device Description:**

The Blackstone™ Spinal Fixation System Staple & Washer (System Modification) are titanium alloy (6AL-4V ELI, per ASTM F136) devices, which are non-sterile, single use components. These devices are an adjunct to the Spinal Fixation System, which allows a surgeon to build a spinal implant construct. The system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space. The devices added to the current Spinal Fixation System are listed below with a brief description.

**Staple:**

The Staple is available in one diameter and three thicknesses. This device may be required in various clinical applications, as determined by a qualified surgeon. The Staple has a conical recess feature, which allows the head of a pedicle screw to nest in it for congruent contact between components. Furthermore, the device has three prongs with a trocar tip which fix's the device to a vertebral body. For the

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actual application of the device refer to the surgical technique in Appendix C, Exhibit I.

The Staple is available in the configurations are as follows:

Spacer 2mm thickness  
 Spacer 4mm thickness  
 Spacer 6mm thickness

**Washer:**

The Washer is available in one diameter and three thicknesses. This device may be required in various clinical applications, as determined by a qualified surgeon. The Washer has a conical recess feature, which allows the head of a pedicle screw to nest in it for congruent contact between components. For the actual application of the device refer to the surgical technique in Appendix C, Exhibit I.

The Washer is available in the configurations are as follows:

Spacer 2mm thickness  
 Spacer 4mm thickness  
 Spacer 6mm thickness

**Intended Use / Indications for Use:**

Blackstone Spinal Fixation System is intended for non-cervical use in the spine.

The Blackstone Spinal Fixation System, when used for anterolateral screw/staple fixation of the T6-L5 spine, is intended for the following indications:

- a) Degenerative disc disease (ddd) – this should be defined. Based on the 5/23/96 Panel meeting, ddd should be defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- b) Spondylolisthesis
- c) Trauma (i.e., fracture or dislocation)
- d) Spinal stenosis;
- e) Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- f) Tumor
- g) Pseudarthrosis
- h) Previous failed fusion.

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**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Blackstone™ Staple & Washer is a system modification to the Blackstone™ Spinal Fixation System, which has received regulatory clearance as follows:

Blackstone™ Spinal Fixation System (K994217)

Blackstone™ Spinal Fixation System Second-Gen Cross-Connector (K003735)

Blackstone™ Spinal Fixation System 4.5mm Mono-Axial Screws (K013558)

Blackstone™ Spinal Fixation System 4.5mm Multi-Axial Screws (K020674)

**510(k) Number:**

**Device Name:** *Blackstone™ Spinal Fixation System*



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 21 2002

Mr. Alan Lombardo  
Director, Engineering  
Blackstone Medical, Inc.  
90 Brookdale Drive  
Springfield, Massachusetts 01104

Re: K022605

Trade/Device Name: Blackstone™ Spinal Fixation System Staple and Washer  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: August 2, 2002  
Received: August 6, 2002

Dear Mr. Lombardo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

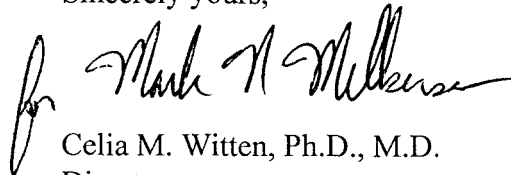
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4539. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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**Indications for Use:**

Blackstone Spinal Fixation System is intended for non-cervical use in the spine.

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- f) Tumor
- g) Pseudarthrosis
- h) Previous failed fusion.

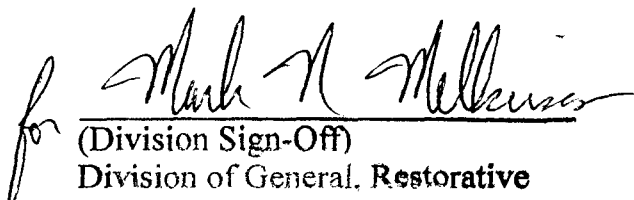
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR801.109)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K022605